Paper No. 26

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte FRANK CAREY, ALEXANDER OLDHAM,
NORMAN E. CAMERON and MARY A COTTER

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Appeal No. 1999-1703
Application No. 08/313,194

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HEARD: September 11, 2001

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Before WINTERS, MILLS and GRIMES, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-5 and 13, which are all of the claims pending in this application.

We reverse.

Claims 1 and 13 are illustrative of the claims on appeal and read as follows:

1. A method of treating or preventing the development of disease conditions associated with impaired neuronal conduction velocity in a warm-blooded animal requiring such treatment which comprises administering to said animal a neuronal conduction velocity enhancing effective amount of an angiotensin II antagonist, or a pharmaceutically acceptable salt thereof.

13. A pharmaceutical composition comprising an angiotensin II antagonist, or a pharmaceutically acceptable salt thereof, together with one or more pharmaceutical agents selected from aldose reductase inhibitors and hypoglycaemic agents.

The prior art reference relied upon by the examiner is:

Bagley et al (Bagley) 5,175,164 Dec. 29, 1992

References relied on by Appellants:

Wyngaarden et al. (Wyngaarden), Textbook of Medicine, Chpt. 218, Diabetes Mellitus, pp. 1307-1309 and 2037-2038. (Date unknown)

Weatherall et al. (Weatherall), Oxford Textbook of Medicine, pp. 3972 and 3993, Oxford Press, New York (1996)

Bartus et al. (Bartus), “The Cholinergic Hypothesis of Geriatric Memory Dysfunction,” Science, Vol. 217, pp. 408-417 (1982)

Collins et al. (Collins), Gray's Anatomy, 38th Ed., Churchill Livingston Pub., pp. 18 and 1819 and 1820 (1995)

Ground of Rejection

Claims 1-5 and 13 stand rejected under 35 U.S.C. § 103(a) as obvious over applicants' admissions (specification pages 1-3) in view of Bagley.

Claim 13 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains or with which it is most nearly connected to make and/or use the invention.

DISCUSSION

In reaching our decision in this appeal, we have given consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the noted rejection, we make reference to the examiner's Answer for the examiner's reasoning in support of the rejection, and to the appellants' Brief for the appellants' arguments thereagainst. As a consequence of our review, we make the determinations which follow.

35 U.S.C. § 103(a)

Claims 1-5 and 13 stand rejected under 35 U.S.C. § 103(a) as obvious over applicants' admissions (specification pages 1-3) in view of Bagley.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. In re Bell, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993). An obviousness analysis requires that the prior art both suggest the claimed subject matter and reveal a reasonable expectation of success to one reasonably skilled in the art. In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

In the present case, the examiner relies on applicants' admissions in the specification at pages 1-3 that "the claimed active agents are known angiotensin II antagonists." Answer, page 3. At the time appellants' invention was made, however, angiotensin II antagonists were known for the treatment of hypertension and congestive heart failure (specification, page 3) but not for treating or preventing the development of disease conditions associated with impaired neuronal conduction velocity. According to the examiner, "Bagley et al Would [sic] motivate the skilled artisan to use angiotensin II antagonists (claims 1-3) and tetrazoles (claims 4-5) to treat impaired neuronal conduction since they teach at column 57, lines 19-37 that compounds similar to applicants are used

to treat diabetic neuropathy". Answer, page 3. The examiner further finds that "[t]he velocity of [sic, that] such action takes places would be inherent in the use thereof." Id.

In their Brief (page 5), appellants acknowledge that A-II antagonists were known in the art, however, they argue that the prior art does not directly teach or suggest that A-II antagonists would be effective in the treatment of conditions associated with impaired neuronal function. The appellants argue that the examiner "appeared to be confusing ‹diabetic nephropathy,' a renal or kidney disease mentioned in Bagley, with ‹diabetic neuropathy,' a disorder of the nervous system..." Id., Note 1 [emphasis original].

In the final rejection, the examiner indicates that Bagley et al. teach at column 1, line 48 to column 2, line 68 that the use of indoles and tetrazoles which are angiotensin II antagonists are useful in the treatment of cognitive dysfunctions including Alzheimer's disease, amnesia and senile dementia. Paper No. 14, page 2. The examiner finds that in view of the teaching of Bagley et al. at column 57, lines 30-35 that the agents set forth therein would treat diabetes would motivate the skilled artisan to treat or prevent diabetic neuropathy since it teaches the treatment of a form of diabetes. According to the examiner, the activity therein would inherently enhance neuronal conduction velocity.

In the present case, the claims are specifically directed to a method of treatment of a specific disorder, treating or preventing the development of disease conditions associated with impaired neuronal conduction velocity in a warm-blooded animal requiring

such treatment which comprises administering to said animal a neuronal conduction velocity enhancing effective amount of an angiotensin II antagonist, or a pharmaceutically acceptable salt thereof.

We find with respect to claims 1-5, that the examiner has failed to establish a prima facie case of obviousness. In particular, although the examiner would suggest that Bagley teaches compounds such as angiotensin II antagonists have central nervous system activity, the examiner has failed to provide evidence that that activity is an enhanced neuronal conduction velocity, as claimed. Moreover, although Bagley would support that A-II antagonists are also useful for the treatment of renal disorders in diabetics, the examiner has not presented evidence, and we do not find support in Bagley that in the treatment of such renal disorders the compounds result in enhanced neuronal conduction velocity.

To punctuate this point, Appellants argue that (Brief, page 9)

> The Examiner has not established any relevant association between the cognitive disorders noted in Bagley with impairment of neuronal conduction velocity, or between diabetic nephropathy or retinopathy associated with Bagley, with the disease conditions associated with impaired neuronal conduction velocity, such as diabetic neuropathy. Any such associated would be refuted, e.g. by Cecil, et al., Textbook of Medicine, 19th ed., (1992), 1307-09, 2037-2038; The Oxford Textbook of Medicine, 3rd ed., page 3972); Bartus et al., Science 1982, Vol. 217 408-417; and Gray's Anatomy, 38th ed. (1995) at 1823, ...

With respect to claim 13, the examiner has not provided any reasoned analysis why it would have been obvious to one of ordinary skill in the art to combine the claimed angiotensin II antagonists with one or more pharmaceutical agents selected from aldose reductase inhibitors and hypoglycaemic agents. In the rejection under 35 U.S.C. § 103(a) the examiner has failed to even address composition claim 13 separate from the method claims.

After evidence or arguments are submitted by the appellants in response to rejection based on obviousness, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of the argument. On balance, we believe that the totality of the evidence presented by the examiner and appellants weighs in favor of finding the claimed invention to be non-obvious in view of the cited references. We find the examiner has not established on the record before us that the cited references both suggest the claimed subject matter and reveal a reasonable expectation of success to one reasonably skilled in the art. The rejection of claims 1-5 and 13 for obviousness of the claimed invention is reversed.

35 U.S.C. 112, first paragraph

Claim 13 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one

skilled in the art to which it pertains or with which it is most nearly connected to make and/or use the invention.

The examiner argues that the specification lacks a teaching of the amounts and which aldose reductase inhibitor or hypoglycaemic agents are to be used in applicants' claimed invention. Answer, page 3.

Appellants respond to this argument, stating that

> The invention of claim 13 lies in recognizing that A-II antagonists are useful in combination with other known agents used for treating or preventing impaired neuronal conduction velocity... [P]ersons skilled in the art wishing to treat or prevent impairment of neuronal conduction velocity could easily select a suitable known aldose reductase inhibitor or hypoglycaemic agent, and could readily select a suitable quantity to be used in the combination of claim 13.

Brief, page 16.

The examiner fails to directly respond to the argument of appellants that persons skilled in the art wishing to treat or prevent impairment of neuronal conduction velocity could easily select a suitable known aldose reductase inhibitor or hypoglycaemic agent, and could readily select a suitable quantity to be used in the combination of claim 13, stating only that “there are various unrelated compounds which are so classified and there is a lack of teaching in the specification of which species would have the claimed effect.” Answer, page 4.

Although not explicitly stated in section 112, to be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without "undue experimentation." Vaeck, 947 F.2d at 495, 20 USPQ2d at 1444; Wands, 858 F.2d at 736-37, 8 USPQ2d at 1404; In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (the first paragraph of section 112 requires that the scope of protection sought in a claim bear a reasonable correlation to the scope of enablement provided by the specification). Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). An analysis of whether the claims under appeal are supported by an enabling disclosure requires a determination of whether that disclosure contained sufficient information regarding the subject matter of the appealed claims as to enable one skilled in the pertinent art to make and use the claimed invention. In order to establish a prima facie case of lack of enablement, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. See In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). See also In re Morehouse, 545 F2d 162, 192 USPQ 29 (CCPA 1976). The threshold step in resolving this issue is to

determine whether the examiner has met his burden of proof by advancing acceptable reasoning inconsistent with enablement. Factors to be considered by the examiner in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman, [230 USPQ 546, 547 (BdPatAppInt 1986)].

In our view, the examiner has failed to establish a prima facie case of lack of enablement by advancing acceptable reasoning inconsistent with enablement, such as providing evidence that there are various unrelated compounds which are classified as known aldose reductase inhibitor or hypoglycaemic agents and that those of skill in the art would not readily understand which species would have the claimed effect. The examiner has failed to enumerate and analyze the relevant Forman factors to determine whether the disclosure would require undue experimentation on the part of one of ordinary skill in the art. Thus, the examiner has failed to meet the burden of putting forward evidence inconsistent with enablement. Accordingly, the rejection of claim 13 for lack of enablement is reversed.

CONCLUSION

The rejection of claims 1-5 and 13 under 35 U.S.C. § 103(a) as obvious over applicants' admissions (specification pages 1-3) in view of Bagley is reversed. The

rejection of claim 13 under 35 U.S.C. § 112, first paragraph for lack of enablement is reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REVERSED

SHERMAN D. WINTERS Administrative Patent Judge	)
DEMETRA J. MILLS Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
ERIC GRIMES Administrative Patent Judge	)

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